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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,192	08/09/2001	Dan W. Denney JR.	GENITOP-06493	5113
7590 10/20/2005 MEDLEN & CARROLL, LLP Suite 350 101 Howard Street San Francisco, CA 94105			EXAMINER YAEN, CHRISTOPHER H	
			ART UNIT 1643	PAPER NUMBER

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,192

Applicant(s)

DENNEY, DAN W.

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/1/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Re: Denney D

1. The amendment filed 8/1/2005 is acknowledged and entered into the record. Accordingly, claims 1-34 are canceled without prejudice or disclaimer.
2. Claims 35-39 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. The Information Disclosure Statement filed 8/1/05 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 35-39 under 35 USC § 112, 1st paragraph is maintained for the reasons of record. Applicant argues that the instant invention is enabled. Specifically applicant argues that based on the credible utility of the claimed invention, the instant invention also has an enabling disclosure for the claimed invention. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Although applicant's amendments and arguments with regard to the utility rejection are deemed persuasive, the claims as currently amended have changed the scope of the invention. As such, the newly amended claims lack an enabling disclosure

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because the specification has not provided any predictable use for the claimed method. Specifically, the specification indicates that the intended use of the claimed method is for the production of custom compositions for the treatment of B-cell lymphoma by eliciting a response to autologous tumor derived Ig or Ig sub-fragments isolated from the subjects B-cell lymphoma (see page 53 for example). The specification although provides sufficient guidance with regard to the production of multivalent vaccines (see examples section) fails to provide sufficient guidance for the use of the multivalent composition following the successful production of said composition. It appears that the composition made by the claimed method of the instant invention is intended to elicit the anti-idiotypic network for the elicitation of an anti-tumor response. However, it is well established in the art that the generation of effective anti-idiotypic antibodies that are capable of acting as antigenic images is rather unpredictable.

The art teaches that the process of generating internal image anti-idiotypic antibodies are well known to those of skill in the art and can result in the production of internal image antibodies that mimic the immunological properties of the initial antigen (i.e., tumor antigen or infectious agent). For support, see Raychaudhuri S., U.S. Patent 5,270,202, bridging paragraph of columns 2-3). Wu, X-R (U.S. Patent 6,632,431 B2) teaches the three types of anti-idiotypic antibodies, alpha ($Ab_2\alpha$), beta ($Ab_2\beta$) and epsilon ($Ab_2\epsilon$) and only $Ab_2\beta$, which binds to the CDR can be an internal image of the antigen and has been proposed to be paratropic and to mimic the molecular features of the original antigen (see column 3, lines 44-58). Raychaudhuri S. acknowledges that the successful production of anti-idiotypic antibodies is an unpredictable endeavor (see

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column 3, lines 35-54). "In short, the discovery of therapeutically useful anti-idiotypic antibodies is as much art as science" (see column 3, lines 49-51). Chatterjee et al (U.S. Patent 6,235,280 B1) teach that not all anti-idiotypic antibodies can be used in therapeutic regimens against tumors. First, only a fraction of antibodies raised against an Ab1 (anti-antigen antibody) are limited in their reactivity to the paratope of Ab1 (i.e., are non-reactive against features shared with other potential antibodies in the host). Second, anti-idiotypic antibodies are not necessarily immunogenic. Third, only a fraction of the immunogenic anti-idiotypes elicit an antigen-specific immune response. Further, anti-idiotypic therapy with respect to tumor origin and antigens expressed should be evaluated on a case-by-case basis since different cancers have widely varying molecular and clinical characteristics (see column 2, lines 39-53).

The specification of the instant invention fails to provide one of skill in the art with any reasonable guidance commensurate in scope to the claimed method of making the multivalent composition that can be predictably used for the generation of an anti-tumor response. Starting at example 10 of the specification, (page 88), the guidance provided appears to be prophetic embodiments of the use of the multivalent composition.

However, this information is not deemed sufficient to enable the use of the multivalent composition in an unpredictable art. As such, applicants have provided insufficient evidence or nexus that would lead the skilled artisan to predict or expect the multivalent composition to be capable of being used as an anti-tumor composition as intended.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue

experimentation in order to practice the claimed invention. Thus the rejection under 35 USC 112, 1st paragraph is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
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October 13, 2005



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER